COPY

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

RELIANT PHARMACEUTICALS, INC., a Delaware Corporation,	)	
Plaintiff,	)	Civil Action No. 04-350
v.	)	
ABBOTT LABORATORIES, an Illinois corporation, and LABORATOIRES FOURNIER S.A., a French corporation,	)	
Defendants.	)	

COMPLAINT

Plaintiff, Reliant Pharmaceuticals, Inc. for its Complaint against defendants Abbott Laboratories and Laboratories Fournier S.A. (hereinafter "Defendants"), alleges as follows:

1. Plaintiff Reliant Pharmaceuticals, Inc. ("Reliant") is a Delaware Corporation having a principal place of business at 110 Allen Road, Liberty Corner, New Jersey 07938.

2. On information and belief, defendant Abbott Laboratories ("Abbott") is a corporation organized under the laws of the State of Illinois, having its principal place of business at 100 Abbott Park Road, Abbott Park, Illinois 60064.

3. On information and belief, defendant Laboratoires Fournier S.A. ("Fournier") is a French corporation having its principal place of business at 42 rue de Longvic, 21300 Chenôve, France, and a place of business in the United States of America, under the alter ego Fournier Pharma Corp., located at 6 Campus Drive, Parsippany, New Jersey, 07054.

JURISDICTION AND VENUE

4. This action for declaratory judgment arises under the patent laws of the United States, 35 U.S.C. §§ 1 *et seq.* and 21 U.S.C. § 355. Subject matter jurisdiction exists pursuant to

28 U.S.C. §§ 1331 and 1338(a), 35 U.S.C. § 271(e)(2) and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. This is a case of actual controversy within the Court's jurisdiction seeking a declaratory judgment of non-infringement, invalidity, and unenforceability of U.S. Patent Nos. 6,074,670 (the "'670 patent"), 6,277,405 (the "'405 patent"), 6,589,552 (the "'552 patent") and 6,652,881 (the "'881 patent").

5. Venue in this judicial district is proper pursuant to 28 U.S.C. §1391 and/or 1400(b). Personal jurisdiction over Defendants comports with the United States Constitution and Delaware's long-arm statute, 10 Del. C. § 3104. Defendants also have subjected themselves to the jurisdiction of this Court by, upon information and belief, commencing several related lawsuits in Delaware, including *Abbott Laboratories, et al., v. Teva Pharmaceuticals USA, Inc.*, C.A. No. 02-1512 (MPT), and *Abbott Laboratories, et al. v. Impax Laboratories*, C.A. No. 03-120 (KAJ), alleging infringement of the same patents for which Plaintiff seeks a declaratory judgment of non-infringement, invalidity and unenforceability in this action.

BACKGROUND

6. On information and belief, Defendant Abbott Laboratories develops, manufactures and markets branded pharmaceutical products. Typically, branded drugs are those that are subject to approval by the United States Food and Drug Administration ("FDA") of a New Drug Application ("NDA"). Once approved, such products generally are referred to as "brand-name" or "branded" drugs because they are marketed under a trade name or trademark for the drug product, rather than the chemical name for the active pharmaceutical ingredient or "drug substance" in the drug product. Non-branded or generic drugs are typically marketed under the chemical name of the active pharmaceutical ingredient in the drug product.

7. Reliant is a privately held pharmaceutical company that exclusively markets branded pharmaceutical products to U.S.-based primary care and targeted specialty physicians.

The Hatch-Waxman Act

8. The Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355 (1994) and 35 U.S.C. § 271(d)-(h) (1995), known as the Hatch-Waxman Act, was enacted in 1984. Section 505 of the Hatch-Waxman Act described three types of new drug applications: (a) an application that contains full reports of investigations of safety and effectiveness (an "NDA"); (b) an application that contains full reports of investigations of safety and effectiveness, but where at least some of the information required for approval comes from studies (i) not conducted by or for the applicant and (ii) for which the applicant has not obtained a right of reference (a "Section 505(b)(2) Application"); and (c) an application that contains information to show that the proposed product is identical in active ingredient, dosage form, strength, route of administration, labeling, quality, performance characteristics, and intended use to a previously-approved product (referred to as an Abbreviated New Drug Application or "ANDA").

9. This action arises out of Reliant's filing of a Section 505(b)(2) Application seeking FDA clearance to market a new drug product where some of the information required for approval comes from studies conducted by or for Abbott and for which Reliant has not obtained a right of reference from Abbott.

10. As a mechanism for resolving patent disputes, the Hatch-Waxman Act requires that the holder of each NDA and Section 505(b)(2) Application submit information about certain patents associated with its branded drug. In particular, brand-name drug manufacturers must file "the patent number and the expiration date of any patent which claims the drug for which the

applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. §355(b)(1).

11. The FDA lists the patent information, including each patent number and expiration date, provided by a brand-name drug manufacturer in a publication entitled, "Approved Drug Products with Therapeutic Equivalence Evaluations" (known throughout the industry as the "Orange Book").

12. Where a 505(b)(2) Application relies upon investigations of safety or efficacy that have been performed by or for the holder of a previously-approved NDA (as opposed to published literature), the applicant must address the Orange Book patent information for any "patent which claims the drug or drugs on which investigations that are relied upon by the applicant for approval of its application were conducted or which claims a use for such drug or drugs." 21 C.F.R. § 314.52(a). In particular, the Hatch-Waxman Act requires an applicant filing a Section 505(b)(2) Application to submit one of four patent certifications:

- a Paragraph I certification stating that no patent information has been filed for the approved drug;
- a Paragraph II certification stating that the patent has expired;
- a Paragraph III certification stating that the patent will expire on a certain date (and that the applicant does not seek approval before that date); or
- a Paragraph IV certification stating that the patent is invalid and/or will not be infringed.

21 U.S.C. § 355(b)(2)(A)(I)-(IV).

13. If a Section 505(b)(2) applicant files a "Paragraph IV" certification stating that it believes that an unexpired patent associated with the previously-approved drug product is invalid, unenforceable, and/or not infringed by its proposed new drug product, a statutory and regulatory framework governing the approval process is triggered. 21 U.S.C. § 355(b)(3); 21 C.F.R. § 314.52.

14. Applicants filing either a Section 505(b)(2) Application or ANDA must give a notice of the "Paragraph IV" certification to the patentee and owner of the NDA under which the corresponding branded product is sold. 21 U.S.C. § 355(b)(3)(A)-(B); 21 C.F.R. § 314.52(a)(1)-(2). That notice must include a detailed statement of the grounds for the belief that the patent is invalid, unenforceable, and/or not infringed. 21 U.S.C. § 355(b)(3)(D)(ii); 21 C.F.R. § 314.52(c)(6).

15. In order to facilitate the orderly resolution of disputes arising out of Paragraph IV certifications without requiring the FDA to make patent-related determinations of law or fact — issues that the FDA has acknowledged are outside the scope of its expertise — the Hatch-Waxman Act included special jurisdictional provisions to allow the federal courts to exercise case or controversy jurisdiction to rule on a Paragraph IV applicant's claims of patent invalidity, unenforceability, or non-infringement before any actual commercial manufacturing or sales of the proposed 505(b)(2) product take place. 35 U.S.C. § 271(e)(2).

16. The patentee may commence an infringement action against the 505(b)(2) applicant within 45 days from the date it receives notice of the Paragraph IV certification. 21 U.S.C. § 355(c)(3)(C). If the patentee brings suit within the 45-day period, the Hatch-Waxman Act prohibits the FDA from approving the 505(b)(2) application for a period of 30 months, unless the litigation is resolved earlier.

17. If a patent holder does not bring a Paragraph IV infringement action within 45 days, the FDA must generally make the approval of the 505(b)(2) application effective immediately upon satisfactory completion of its substantive review. 21 U.S.C. § 355(b)(3).

18. The Hatch-Waxman Act bars all parties from bringing a declaratory judgment action for patent invalidity, unenforceability, or non-infringement until after the expiration of the 45-day period following the patent-holder's receipt of notice of a Paragraph IV certification. 21 U.S.C. § 355(c)(3)(D)(I).

EXISTENCE OF CAUSE OF ACTION CONTROVERSY

19. Pharmaceutical products containing the drug substance fenofibrate are prescribed as a lipid and cholesterol lowering agent for adults with increased triglyceride levels. The drug substance fenofibrate is in the public domain and not protected by claims of any valid and existing patents.

20. Abbott currently sells a fenofibrate tablet product in the United States under the brand name Tricor®. Tricor® fenofibrate tablets were approved for sale by the FDA under NDA No. 21-203. On information and belief, Abbott listed at least five patents in the Orange Book with respect to NDA No. 21-203. They are United States Patent Nos. 4,895,726 (the "'726 patent"), the '670 patent, the '405 patent, the '552 patent and the '881 patent.

21. Fournier is the owner by assignment of the '670 patent, the '405 patent, the '552 patent and the '881 patent (collectively, the "Patents in Suit").

22. Upon information and belief, Abbott is the exclusive licensee in the United States of the Patents in Suit.

23. The Patents in Suit all claim fenofibrate dosage forms with specific formulation characteristics.

24. Abbott previously sold a capsule version of a fenofibrate product under the Tricor® brand name. Abbott's Tricor® fenofibrate capsules were approved for sale by the FDA under NDA No. 19-304. NDA No. 19-304 is listed in the Orange Book by the FDA as a "discontinued product," although generic versions of that product are currently approved for sale by the FDA.

25. The only patent listed in the Orange Book concerning NDA 19-304 is the '726 patent. The '726 patent claims fenofibrate formulations containing fenofibrate and a solid surfactant that have been "co-micronized" (defined by the inventors as "the micronization of an intimate mixture of fenofibrate and a solid surfactant") to increase the bioavailability of the product.

26. In February 2004, Reliant received notice from the FDA that the agency had accepted for filing Reliant's Section 505(b)(2) Application, NDA No. 21-695, seeking approval of a new fenofibrate capsule product preliminarily named "RP 1824." Reliant's Section 505(b)(2) Application for RP 1824 relies upon studies that were performed by or on behalf of Abbott to establish the safety and efficacy of Abbott's discontinued fenofibrate capsule product approved under NDA 19-304.

27. Reliant filed a Paragraph IV certification with respect to the '726 patent in its Section 505(b)(2) application, certifying that, to the best of Reliant's knowledge and belief, the importation, manufacture and sale of RP 1824 would not infringe the '726 patent. Reliant provided the requisite notice of its filing and Paragraph IV certification to Abbott and Fournier.

28. In Reliant's notice letter to Abbott and Fournier with respect to the '726 patent, Reliant offered to provide documents to Abbott and Fournier's outside counsel demonstrating

that RP 1824 would not infringe any of the claims of the '726 patent including an "offer of confidential access" to the 505(b)(2) Application pursuant to Section 355(b)(3)(D)(i)(III).

29. In response, by letter dated March 1, 2004, counsel for Abbott and Fournier rejected the terms of Reliant's offer for confidential access, arguing that Abbott and Fournier should not be limited in their confidential examination of Reliant's application solely to an analysis of the non-infringement of the '726 patent, and asserting that Abbott and Fournier would "only accept these samples and information under terms that allow us to use the samples and information to perform an infringement analysis with respect to any and all of Abbott's and Fournier's patent rights."

30. Abbott and Fournier reiterated this demand in another letter dated March 16, 2004, in which Abbott and Fournier stated that:

> Reliant's effort to prevent Abbott and Fournier from evaluating infringement under patents other than the '726 patent until *after* the 45-day period expires raises serious concerns on our part. It is impeding Abbott and Fournier's evaluation of infringement of the '726 patent by Reliant. What is more, it heightens our concern about the propriety of Reliant's decision to provide a Paragraph IV certification only with respect to the '726 patent (which is the patent listed in the *Orange Book* for Abbott's NDA 19-304) without providing a Paragraph IV certification with respect to the '670 patent; the 405 patent; the '552 patent; and the '881 patent, which are listed in the Orange Book for Abbott's NDA 21-203 along with the '726 patent. . . .
>
> In order for Abbott and Fournier to evaluate infringement for infringement [sic] of the patents that are listed in the Orange Book for NDA 21-203, we demand that Reliant produce the materials requested in my March 1, 2004 letter no later than Friday, March 19, 2004, under terms allowing Abbott and Fournier's outside counsel, in-house counsel (who are not involved in any competitive decision making role concerning fenofibrate), and outside independent experts access to the materials for the purpose of evaluating infringement of any of Abbott and Fournier's patent rights. If Reliant does not comply with this request, we reserve the right to seek appropriate recourse.

31. Abbott and Fournier reiterated their March 1 demand for samples of RP 1824 in a letter dated April 7, 2004. To date, Reliant has not provided such samples to Abbott and Fournier.

32. Abbott and Fournier's assertion that "[they] reserve the right to seek appropriate recourse" is a thinly-veiled threat that Abbott and Fournier will bring a patent infringement action against Reliant if Reliant fails to produce a sample of RP 1824 for Abbott's and Fournier's examination and comply with additional, litigation-minded demands.

33. Abbott and Fournier have already asserted the Patents in Suit against Cipher Pharmaceuticals Ltd., another filer of a Section 505(b)(2) application for a fenofibrate dosage form, in an action pending in the United States District Court for the District of Puerto Rico, Case No. 3:03-cv-01421 (DRD)(the "Cipher Litigation"). In the Cipher litigation, Abbott and Fournier assert the same patents as the Patents in Suit against another proposed Section 505(b)(2) fenofibrate product.

34. In late 2003, Cipher announced that Reliant would be the United States distributor of the proposed Cipher fenofibrate product. Subsequently, Abbott and Fournier served a subpoena dated March 3, 2004 on Reliant in connection with the Cipher Litigation, demanding, among other things, access to "all documents relating to fenofibrate products" in Reliant's possession, custody or control. This subpoena obviously calls for all documents relating to both the Cipher fenofibrate product as well as RP 1824, despite the fact that Abbott and Fournier are fully aware that the Cipher fenofibrate product is the subject of an entirely different Section 505(b)(2) application.

35. Abbott and Fournier have similarly asserted the Patents in Suit against at least four generic ANDA applicants: Teva Pharmaceuticals USA, Inc., Par Pharmaceutical, Inc., Impax Laboratories, and Ranbaxy Pharmaceuticals.

36. On information and belief, Abbott and Fournier intend to bring an action for infringement against Reliant with respect to the Patents in Suit in order to prevent the importation, manufacture, offer for sale, and sale of RP 1824, which would compete against Abbott's Tricor products in the United States market for fenofibrate dosage forms.

37. Abbott's and Fournier's conduct is sufficient to indicate their intent to enforce the Patents in Suit against Reliant.

38. Reliant has an objectively reasonable apprehension that Abbott and Fournier will sue Reliant to enforce the Patents in Suit.

THE PATENTS IN SUIT

The '670 Patent

39. The '670 patent, entitled "Fenofibrate Pharmaceutical Composition Having High Bioavailability and Method for Preparing it" issued on June 13, 2000 to Andre Stamm and Pawan Seth. Its owner by assignment is Fournier. On information and belief, Abbott is the exclusive licensee of the '670 patent. A true and correct copy of the '670 patent is attached hereto as Exhibit A.

40. The '670 patent contains 38 claims, only two of which (Claims 1 and 12) are independent. Claim 1 of the '670 patent recites:

> [a]n immediate-release fenofibrate composition comprising:
>
> (a) an inert hydrosoluble carrier covered with at least one layer containing fenofibrate in a micronized form having a size less than 20μm, a hydrophilic polymer and a surfactant; and

(b) optionally one or several out phase(s) or layer(s), wherein, based on the weight of (a), said inert hydrophilic carrier makes up from 20 to 50% by weight, said fenofibrate makes up from 20 to 45% by weight, said hydrophilic polymer makes up from 20 to 45% by weight, and said surfactant makes up from 0.1 to 3% by weight.

41. Similarly, Claim 12 recites an immediate release fenofibrate composition that includes polyvinylpyrrolidone ("PVP"), a specific type of hydrophilic polymer, which constitutes between 20% and 45% of the composition by weight.

42. Reliant's proposed RP 1824 product does not infringe any valid claim of the '670 patent.

The '405 Patent

43. The '405 patent entitled "Fenofibrate pharmaceutical composition having high bioavailability and method for preparing it" issued on August 21, 2001 to Andre Stamm and Pawan Seth. Its owner by assignment is Fournier. On information and belief, Abbott is the exclusive licensee of the '405 patent. A true and correct copy of the '405 patent is attached hereto as Exhibit B.

44. Claim 1 of the '405 patent, the sole independent claim, is as follows:

> A composition comprising a hydrosoluble carrier and micronized fenofibrate having a dissolution of at least 10% in 5 minutes, 20% in 10 minutes, 50% in 20 minutes and 75% in 30 minutes, as measured using the rotating blade method at 75 rpm according to the European Pharmacopoeia, in a dissolution medium constituted by water with 2% by weight polysorbate 80 or with 0.025M sodium lauryl sulfate.

Claims 2-13 depend from claim 1, either directly or indirectly.

45. Reliant's proposed RP 1824 product does not infringe any valid claim of the '405 patent.

The '552 Patent

46. The '552 patent entitled "Fenofibrate pharmaceutical composition having high bioavailability and method for preparing it" issued on July 8, 2003 to Andre Stamm and Pawan Seth. Its owner by assignment is Fournier. On information and belief, Abbott is the exclusive licensee of the '552 patent. A true and correct copy of the '552 patent is attached hereto as Exhibit C.

47. The '552 patent contains 57 claims, only three of which (Claims 1, 31 and 57) are independent. Claim 1 of the '552 patent is as follows:

> A fenofibrate composition comprising granulates, wherein the granulates comprise micronized fenofibrate having a particle size below 20 μm, inert hydrosoluble carrier particles and at least 20% by weight of at least one hydrophilic polymer, wherein the weight ratio of fenofibrate to hydrophilic polymer is from 1/10 to 4/1.

Claims 2-30 and 56 depend from claim 1, either directly or indirectly.

48. Similarly, claim 31 recites a fenofibrate composition where the hydrophilic polymer is polyvinylpyrrolidone. Claims 32-55 depend directly from claim 31.

49. Similarly, claim 57 recites a fenofibrate composition "wherein the weight ratio of surfactant to hydrophilic polymer is from 1/500 to 1/10."

50. Reliant's proposed RP 1824 product does not infringe any valid claim of the '552 patent.

The '881 Patent

51. The '881 patent entitled "Fenofibrate pharmaceutical composition having high bioavailability" issued on November 25, 2003 to Andre Stamm and Pawan Seth. Its owner by assignment is Fournier. On information and belief, Abbott is the exclusive licensee of the '881 patent. A true and correct copy of the '881 patent is attached hereto as Exhibit D.

52. The '881 patent contains 41 claims, only eight of which (Claims 1, 6, 11, 15, 22, 27, 32 and 37) are independent. Claim 1 of the '881 patent is as follows:

> A composition comprising micronized fenofibrate, wherein the composition has a dissolution of at least 10% in 5 minutes, 20% in 10 minutes, 50% in 20 minutes and 75% in 30 minutes, as measured using the rotating blade method at 75 rpm according to the European Pharmacopoeia, in a dissolution medium constituted by water with 2% by weight polysorbate 80 or 0.025 M sodium lauryl sulfate.

Claims 2-5 depend directly from claim 1.

53. Similarly, claim 6 recites an orally administrable tablet comprising micronized fenofibrate. Claims 7-10 depend directly from claim 6.

54. Similarly, claim 11 recites a composition comprising micronized fenofibrate and at least one polymer. Claims 12-14 depend directly from claim 11.

55. Similarly, claim 15 recites composition comprising at least one inert carrier and one or more outer layers comprising micronized fenofibrate. Claims 16-21 depend directly from claim 15.

56. Similarly, claim 22 recites a composition comprising granulates which comprise micronized fenofibrate. Claims 23-26 depend directly from claim 22.

57. Similarly, claim 27 recites an orally administrable tablet comprising granulates, wherein the granulates comprise micronized fenofibrate. Claims 28-31 depend directly from claim 27.

58. Similarly, claim 32 recites an orally administrable capsule comprising granulates, wherein the granulates comprise micronized fenofibrate. Claims 33-36 depend directly from claim 32.

59. Similarly, claim 37 recites a granulate comprising micronized fenofibrate. Claims 38-41 depend directly from claim 37.

60. Reliant's proposed RP 1824 product does not infringe any valid claim of the '881 patent.

FIRST CAUSE OF ACTION

Declaratory Judgment of Non-Infringement and Invalidity of United States Patent No. 6,074,670

61. Reliant repeats and realleges the allegations of paragraphs 1-60 above.

62. An actual controversy exists between Reliant and Abbott under 35 U.S.C. § 271(e)(2) with respect to the '670 patent because Abbott and Fournier have (a) represented to Reliant that Reliant should have filed a Paragraph IV certification with respect to the '670 patent; (b) implicitly threatened to commence an action for infringement against Reliant unless Reliant produces samples of RP 1824 for Abbott's and Fournier's examination; (c) commenced an action against Cipher Pharmaceuticals under the same patents and with respect to a fenofibrate product; (d) demanded copies of documents relating to RP 1824 in the Cipher Litigation; and (e) commenced actions for infringement of the Patents in Suit against several generic ANDA applicants. Reliant, therefore, has a reasonable apprehension that Abbott and Fournier will sue Reliant to enforce the Patents in Suit.

63. Reliant's NDA No. 21-695 for RP 1824 does not seek FDA approval for a pharmaceutical composition that infringes any valid claim of the '670 patent.

64. The '670 patent is invalid in that it fails to comply with one or more of the requirements of 35 U.S.C. §§ 101, 102, 103 and/or 112.

SECOND CAUSE OF ACTION

Declaratory Judgment of Non-Infringement and Invalidity of United States Patent No. 6,277,405

65. Reliant repeats and realleges the allegations of paragraphs 1-64 above.

66. An actual controversy exists between Reliant and Abbott under 35 U.S.C. § 271(e)(2) with respect to the '405 patent because Abbott and Fournier have (a) represented to Reliant that Reliant should have filed a Paragraph IV certification with respect to the '405 patent; (b) implicitly threatened to commence an action for infringement against Reliant unless Reliant produces samples of RP 1824 for Abbott's and Fournier's examination; (c) commenced an action against Cipher Pharmaceuticals under the same patents and with respect to another fenofibrate product; (d) demanded copies of documents relating to RP 1824 in the Cipher Litigation; and (e) commenced actions for infringement of the Patents in Suit against several generic ANDA applicants.

67. Reliant's NDA No. 21-695 for RP 1824 does not seek FDA approval for a pharmaceutical composition that infringes any valid claim of the '405 patent.

68. The '405 patent is invalid in that it fails to comply with one or more of the requirements of 35 U.S.C. §§ 101, 102, 103 and/or 112.

THIRD CAUSE OF ACTION

Declaratory Judgment of Non-Infringement and Invalidity of United States Patent No. 6,589,552

69. Reliant repeats and realleges the allegations of paragraphs 1-68 above.

70. An actual controversy exists between Reliant and Abbott under 35 U.S.C. § 271(e)(2) with respect to the '552 patent because Abbott and Fournier have (a) represented to Reliant that Reliant should have filed a Paragraph IV certification with respect to the '552 patent;

(b) implicitly threatened to commence an action for infringement against Reliant unless Reliant produces samples of RP 1824 for Abbott's and Fournier's examination; (c) commenced an action against Cipher Pharmaceuticals under the same patents and with respect to another fenofibrate product; (d) demanded copies of documents relating to RP 1824 in the Cipher Litigation; and (e) commenced actions for infringement of the Patents in Suit against several generic ANDA applicants. Reliant, therefore, has a reasonable apprehension that Abbott and Fournier will sue Reliant to enforce the Patents in Suit.

71. Reliant's NDA No. 21-695 for RP 1824 does not seek FDA approval for a pharmaceutical composition that infringes any valid claim of the '552 patent.

72. The '552 patent is invalid in that it fails to comply with one or more of the requirements of 35 U.S.C. §§ 101, 102, 103 and/or 112.

FOURTH CAUSE OF ACTION

Declaratory Judgment of Non-Infringement and Invalidity of United States Patent No. 6,652,881

73. Reliant repeats and realleges the allegations of paragraphs 1-72 above.

74. An actual controversy exists between Reliant and Abbott under 35 U.S.C. § 271(e)(2) with respect to the '881 patent because Abbott and Fournier have (a) represented to Reliant that Reliant should have filed a Paragraph IV certification with respect to the '881 patent; (b) implicitly threatened to commence an action for infringement against Reliant unless Reliant produces samples of RP 1824 for Abbott's and Fournier's examination; (c) commenced an action against Cipher Pharmaceuticals under the same patents and with respect to another fenofibrate product; (d) demanded copies of documents relating to RP 1824 in the Cipher Litigation; and (e) commenced actions for infringement of the Patents in Suit against several generic ANDA

applicants. Reliant, therefore, has a reasonable apprehension that Abbott and Fournier will sue Reliant to enforce the Patents in Suit.

75. Reliant's NDA No. 21-695 for RP 1824 does not seek FDA approval for a pharmaceutical composition that infringes any valid claim of the '881 patent.

76. The '881 patent is invalid in that it fails to comply with one or more of the requirements of 35 U.S.C. §§ 101, 102, 103 and/or 112.

FIFTH CAUSE OF ACTION

Declaratory Judgment of Unenforceability as to all Patents in Suit

77. Reliant repeats and realleges the allegations of paragraphs 1-76 above.

78. An actual controversy exists between Reliant and Abbott under 35 U.S.C. § 271(e)(2) with respect to the Patents in Suit because Abbott and Fournier have (a) represented to Reliant that Reliant should have filed a Paragraph IV certification with respect to the Patents in Suit; (b) implicitly threatened to commence an action for infringement against Reliant unless Reliant produces samples of RP 1824 for Abbott's and Fournier's examination; (c) commenced an action against Cipher Pharmaceuticals under the same patents and with respect to another fenofibrate product; (d) demanded copies of documents relating to RP 1824 in the Cipher Litigation; and (e) commenced actions for infringement of the Patents in Suit against several generic ANDA applicants. Reliant, therefore, has a reasonable apprehension that Abbott and Fournier will sue Reliant to enforce the Patents in Suit.

79. The '670 patent, the '405 patent, the '552 patent and the '881 patent are unenforceable due to inequitable conduct by the inventors before the United States Patent and Trademark Office. The specifications for each of those patents misrepresent the dissolution profile for a prior art product known as Lipanthyl 200M. Specifically, Figures 1 and 2 in each of

these patents compares the dissolution profiles for the alleged invention to that of the prior art Lipanthyl 200M. The inventors, with the intent to deceive the PTO, misrepresented the dissolution profile for Lipanthyl 200M and furthermore misrepresented that the dissolution profile for the alleged invention was "distinctly better" than that for Lipanthyl 200M.

80. In addition, during the prosecution of at least the '670 patent, the '405 patent, and the '881 patent, the inventors, with intent to deceive the PTO, overcame the Patent Examiner's rejections of certain claims by misrepresenting the dissolution profile for Lipanthyl 200M in the following documents:

a. Response and Amendment under 37 C.F.R. § 1.111, dated December 4, 1998, during prosecution of the application that became the '670 patent;

b. Response and Amendment under 37 C.F.R. § 1.111, dated May 20, 1999, during prosecution of the application that became the '670 patent;

c. Reply under 37 C.F.R. § 1.111, dated November 17, 1999, during prosecution of the application that became the '670 patent;

d. Request for Reconsideration under 37 C.F.R. § 1.111, dated June 25, 2003, during prosecution of the application that became the '881 patent ; and

e. Response and Amendment under 37 C.F.R. § 1.111, dated January 26, 2001, during prosecution of the application that became the '405 patent .

81. The '552 patent is intimately related to the '670 patent, the '405 patent, and the '881 patent because it is a continuation of the other three patents and furthermore has the same subject matter, the same inventors, the same specification, and relies on the same misrepresented prior art. The inventors' broad pattern of inequitable conduct before the United States Patent and

Trademark Office in their prosecution of the '670 patent, the '405 patent, and the '881 patent has tainted the '552 patent so as to render it unenforceable.

82. The '670 patent, the '405 patent, the '881 patent, and the '552 patent are intimately related to each other because the latter three are continuations of the '670 patent and furthermore each patent has the same subject matter, the same inventors, the same specification, and relies on the same misrepresented prior art. The inventors' inequitable conduct before the United States Patent and Trademark Office in their prosecution of each of the '670 patent, the '405 patent, the '881 patent and the '552 patent has tainted the other three so as to render them unenforceable.

REQUEST FOR RELIEF

WHEREFORE, Reliant respectfully requests that this Court enter judgment:

(a) declaring that Reliant's fenofibrate product described in NDA No. 21-695 does not infringe any valid and enforceable claim of United States Patent Nos. 6,074,670, 6,277,405, 6,589,552 or 6,652,881;

(b) declaring that United States Patent Nos. 6,074,670, 6,277,405, 6,589,552 and 6,652,881 are unenforceable due to inequitable conduct before the United States Patent and Trademark Office;

(c) awarding Reliant its reasonable costs and attorneys' fees in connection with this action; and

(d) awarding Reliant such other and further relief as this Court deems just and proper.

POTTER ANDERSON & CORROON LLP

BY: _____

Philip A. Rovner (#3215)
Hercules Plaza
1313 N. Market Street
P.O. Box 951
Wilmington, DE 19899
(302) 984-6000

Attorneys for Plaintiff
Reliant Pharmaceuticals, Inc.

OF COUNSEL:

Andrew M. Berdon
Edward DeFranco
QUINN EMANUEL URQUHART OLIVER & HEDGES LLP
335 Madison Avenue
New York, New York 10017
(212) 702-8100

Dated: June 1, 2004
634135